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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,207	03/16/2004	Bey-Dih Chang	SEN-001US3	3124

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EXAMINER	
MARVICH, MARIA	
ART UNIT	PAPER NUMBER
1633	

MAIL DATE	DELIVERY MODE
09/28/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/801,207	CHANG ET AL.	
	Examiner	Art Unit	
	MARIA B. MARVICH	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7/9/09*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6-8,26,27 and 29-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6-8, 26, 27 and 29-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *3/16/04* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/9/09 has been entered.

Claims 1, 6-8, 26, 27 and 29-31 are pending.

Applicants' amendment has overcome the claim objections with the exception of one noted below as well as the claim rejections under 35 USC 112, second paragraph. Applicants amendment to limit the gene to be assayed as one known to be regulated by p21 is successful in overcoming the rejection under 35 USC 102.

Claim Objections

Claims 1 and 26 are objected to because of the following informalities: upon reconsideration, the following amendments are proposed to provide clarity and accuracy to the claims.

It was previously recommended that the claims be amended to clarify that the method is a screen for those compounds that function as an inhibitor (promoter) of p21 mediated induction. The objection was not due to the use of the terms inhibitor or promoter versus inhibits or promoters. Rather , the claims are unclear in reference to "a compound" as both that that is identified and as that that is assayed. It is recommended that the two be referenced distinctly. As an alternative, the preamble reference to "a compound that inhibits p21 mediated induction"

remaining, the reference within the claims to "the compound" should be amended to --a test compound-- in line 4 and as --the test compound--in line 6, 10, 12 and 17. Not all compounds will act as inhibitors or promoters rather, those that do are identified.

As well, the preamble should be amended to recite for consistency with line 17, -- A method for identifying a compound that inhibits induction or p21 mediated repression of senescence associated changes--. Line 17 for further clarification can be amended simply to recite --identifying the test compound as the compound that inhibits--. Similarly amendment as recommended above is required for claim 26

The word --of-- is missing in line 12 prior to the phrase "the compound".

Clarity by simplification to claim 27 can be achieved by amendment to --wherein the cellular gene is induced by p21--.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by West et al (US 5,482,838; see entire document) as evidenced by McConnell et al (**Current Biology** 1998, 8:351–354). **This is a new rejection.**

West et al teach methods of assaying cells for expression of PAI-1 or βAPP, two genes regulated by p21, in the presence of compounds. Specifically, in column 2, line 26, West et al teach addition of an agent that is able to down regulate expression of PAI-1 and βAPP in senescent cells. As well, in column 4, line 45, West et a propose methods of screening for such agents that down regulate the expression of these proteins. Referring to example 3, the method requires treatment of senescent cells, which inherently are treated or grown under conditions that lead to senescence. Expression of PAI-1 is assayed in the presence and absence of the compound. As the level of the gene is less then the level of non-treated, the agent can be assessed as an inhibitor of p21 mediated induction of senescence associated changes in cellular gene expression. As evidenced by McConnell et al, replicative senescence in these cells is mediated by p21 which also regulates expression of PAI during such events.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over West et al (US 5,482,838; see entire document) as evidenced by McConnell et al (**Current Biology**

1998, 8:351–354) in view of West et al (Experimental Gerontology, Vol. 31, Nos. 1/2, pp. 175-193, 1996.) **This is a new rejection.**

Applicants claim a method of identifying compounds that induce senescence by assaying for activity of a cellular gene product or by use of immunological reagents or by measuring activity of the proteins.

The teachings of West et al as evidenced by McConnell et al are described above and are applied as before except neither teaches detection of PAI-1 by use of immunological reagents or measuring activity of the proteins.

West et al teach induction of senescence and identification of associated gene expression changes which are detected by hybridization as well as immunological reagents and measuring activity of the proteins (see e.g. figures 1, 3, 6 and 7).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to assay for inhibitors of senescence as in the methods of Fisher and Jiang using the assay of gene activity as taught by Beug et al because Fisher and Jiang teach that it is within the ordinary skill of the art to induce senescence and assay for induction of gene expression of senescence related genes and then to identify inhibitors of senescence and because Beug et al teach that it is within the ordinary skill of the art to assay activity of a cellular product as an indication of a cellular event. One would have been motivated to do so in order to receive the expected benefit of ease of detection using reporter gene assays in which gene function is assayed. As well, it would have been of the ordinary skill in the art to substitute one known method for another given that both methods are well known in the art. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the

contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Claims 1, 6, 8, 26, 27 and 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al (US 6,372,249; see entire document) in view of West et al (US 5,482,838; see entire document) as evidenced by McConnell et al (**Current Biology** 1998, 8:351–354) further in view of West et al (Experimental Gerontology, Vol. 31, Nos. 1/2, pp. 175-193, 1996.) **This is a new rejection.**

Applicants claim a method of identifying compounds that induce senescence by assaying for activity of a cellular gene product or by use of immunological reagents or by measuring activity of the proteins.

Smith et al teach induction of p21 mediated senescence in addition to identification of compounds that induce quiescence (see e.g. col 13, lines 20-37). Smith et al do not teach use of assay for activity of a cellular gene product or by use of immunological reagents or by measuring activity of the proteins that are related to senescence.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to assay for inducers of senescence as taught by Smith et al using the methods of West et al in view of West et al because West et al teach that it is within the ordinary skill of the art to induce senescence and assay for induction of gene expression of senescence related genes or by using immunological agents or by measuring marker activity and because Beug et al teach that it is within the ordinary skill of the art to use induction of senescence as a means to therapeutically treat conditions. One would have been motivated to do so in order to receive the expected

benefit of ease of detection using reporter gene assays or in which gene function is assayed. As well, it would have been of the ordinary skill in the art to substitute one known method for another given that both methods are well known in the art. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101, which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 6-8 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 4-8 and 11-14 of U.S. Patent No. 6, 706,491. **This rejection is maintained for reasons of record in the office action mailed 3/20/08 and restated below.**

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claim is either anticipated by, or would have been obvious over, the reference claims. Although the conflicting claims are not identical, they are not patentably distinct from each other because the cited claims of the instant invention are generic to all that is recited in claims. That is, claims 1, 2, 4-8 and 11-14 of U.S. Patent No. 6, 706,491 anticipate and fall entirely within the scope of the rejected claims of the instant application. Specifically, U.S. Patent No. 6, 706,491 and the instant claims recite a method comprising treatment of a mammalian cell such that p21 is induced (the instant claims recite that senescence is induced which is a p21 related event) and then assay for genes induced by p21 in the presence and absence of test compounds. The method of the instant claims identifies inhibitors of senescence, which is inherent in the method of U.S. Patent No. 6, 706,491 that identifies inhibitors of p21.

Additionally, if a patent resulting from the instant claims was issued and transferred to an assignee different from the assignee holding a patent from U.S. Patent No. 6, 706,491, then two different assignees would hold a patent to the claimed invention of U.S. Patent No. 6, 706,491, and thus improperly there would be possible harassment by multiple assignees.

Response to Argument

Rejection under the obviousness type double patenting based upon US application 09/861,925 and 10/233, 032 has been withdrawn due to abandonment. IN the amendment filed 5/6/09, applicants have stated that hey have filed a terminal disclaimer to address the remaining

obviousness double patenting rejections upon indication of allowable subject matter. However, a terminal disclaimer has not been filed, therefore, the claims remain rejected.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARIA B. MARVICH whose telephone number is (571)272-0774. The examiner can normally be reached on M-F (7:00-4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, PhD can be reached on (571)-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maria B Marvich, PhD
Primary Examiner
Art Unit 1633

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